IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF UTAH

CENTRAL DIVISION

NEXMED HOLDINGS, INC., Plaintiff, vs. BETA TECHNOLOGIES, INC. and CHESTER HEATH, Defendants.	MEMORANDUM DECISION and ORDER Case No. 2:06-CV-1014-TC-DN

INTRODUCTION

NexMed Holdings, Inc. (NexMed) brought suit against Beta Technologies, Inc. (Beta) and Chester Heath, the president of Beta, claiming that Beta and Mr. Heath are selling two products, the Cold Sore Inhibitor and the Viral Inhibitor Pro (collectively the "Beta Device"), that infringe on U.S. Patent No. 5,133,352 (the '352 patent), owned by NexMed.

Beta and Mr. Heath have filed several motions for summary judgment: Motion for Summary Judgment on (1) Induced and Direct Infringement, (2) Prosecution History Estoppel, (3) Non-Ownership of Patent, (4) Public Use Invalidity, (5) Non-Usefulness Invalidity, (6) Fraud on the USPO, and (7) Failure to Join Inventor; Motion for Summary Judgment on Claim 13 Violates 35 U.S.C. § 112 (2)(4); Motion for Summary Judgment on Intervening Rights; Motion for Summary Judgment on Willful Infringement; Motion for Partial Summary Judgment on Denial of Injunctive Relief and Limitations on Monetary Relief; and Motion for Summary Judgment on Net Cash Flow Basis for Damages. These motions seek to invalidate the patent on

various grounds and to limit liability in the event infringement is found.

NexMed brings two motions for summary judgment on three of Defendants' affirmative defenses. In their Motion for Summary Judgment Regarding Defendants' Eleventh and Fourteenth Affirmative Defenses, NexMed argues that it did not engage in inequitable conduct or patent misuse as a matter of law. In its Motion for Summary Judgment Regarding Defendants' Second Affirmative Defense, NexMed contends that the'352 patent indisputably satisfies the "machine-or-transformation" test, which defeats the Defendants's' claim that the '352 Patent fails to meet the requirements for patentability set forth in 35 U.S.C. § 101.

BACKGROUND

The '352 patent describes a method to treat skin conditions caused by the herpes virus by sending an electrical current through the affected area. The original patent issued April 12, 1990, to inventors Dr. Peter Lathrop and Steven Johnston. During the original patent examination, Dr. Lathrop and Mr. Johnston sought to include both device claims and method claims, but during prosecution of the patent, they surrendered the device claims. Consequently, the '352 patent has only method claims.

In 1991, Dr. Lathrop and Mr. Johnston transferred ownership of the patent to a partnership that included Dr. Lathrop, Mr. Johnston and Gloria Kent. The partnership later transferred ownership of the patent back to Dr. Lathrop and Mr. Johnston individually. Dr. Lathrop and Mr. Johnston then sold the patent to Target Capital in return for stock and cash. Target Capital changed its name several times and eventually became NexMed.

Nearly a year before filing this action, NexMed prevailed in an infringement suit against Block Investment and Clealon Mann for marketing a similar device with accompanying instructions that induced infringement of the '352 patent. NexMed v. Block Investment Inc., No.

2:04cv00288, Judgment March 1, 2006 (the "0288 litigation"). The court entered a directed verdict in favor of NexMed on the direct and induced infringement claims, and the jury found willful infringement and assessed damages. Although Mr. Heath was a witness for the defense in the previous litigation and was aware of its outcome, he and Beta were not party to that litigation nor were they subject to the injunction that resulted. Id. at Order April 28, 2009.

The '352 patent underwent reexamination proceedings before the patent examiner in 2007 and 2009. The 2007 proceeding resulted in the cancellation of several claims from the original patent and the amendment of other claims. Claims 5-7 are particularly relevant to this lawsuit. In the original '352 patent, claims 6 and 7 were dependant on claim 5. During the first reexamination, the patent examiner cancelled claim 6 from the original patent, which contained a duration of electrical current requirement and an interval of application requirement. In the amended patent, the requirements from claim 6 were added to claim 7, which became an independent claim, and the spacing requirements that remained in the original claim 7 were duplicated in claim 5. The 2009 reexamination confirmed the patentability of the claims as amended in the 1st reexamination certificate.

Mr. Heath and Beta advertise the Beta Device as a method to prevent or limit the severity of lesions caused by the Herpes virus. The instructions that accompany the Beta Device direct the user to place fixed plastic probes around the infected area and then press the "start" button. The Beta Device comes programmed to administer an electrical current for a fixed period of time in one direction and then in the opposite direction. The instructions direct the user to apply the electrical current "HOURLY if late and open sores, or Half Hourly if early and tingling."

SUMMARY JUDGMENT STANDARD

The court should grant summary judgment "if the pleadings, depositions, answers to

interrogatories, and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c).

"[T]he moving party bears the initial burden of presenting evidence to show the absence of a genuine issue of material fact." Trainor v. Apollo Metal Specialties, Inc., 318 F.3d 976, 979 (10th Cir. 2002). To show that no genuine issue of material fact exists, the moving party has "the initial burden of production . . . and the burden of establishing that summary judgment is appropriate as a matter of law." Pelt v. Utah, 539 F.3d 1271, 1280 (10th Cir. 2008). The burden of production is the burden of "both producing additional evidence and presenting persuasive argument based on new evidence or evidence already of record, as the case may require." Tech. Licensing Corp. v. Videotek, 545 F.3d 1316, 1327 (Fed. Cir. 2008). If the moving party bears the ultimate burden of persuasion at trial on the issue for which summary judgment is sought, it cannot shift the burden of production "merely by pointing to parts of the record that it believes illustrate the absence of a genuine issue of material fact." Id. Rather, the burden of production on such an issue shifts to the nonmoving party only after the moving party has "establish[ed], as a matter of law, all essential elements of the issue." Id. At trial, the plaintiff has the burden to prove each of its claims against an alleged infringer, while the defendant has the burden to "prove all elements of the [affirmative] defense." Stockton East Water Dist. v. United States, 583 F.3d 1344, 1360 (Fed. Cir. 2009).

"When an alleged infringer attacks the validity of an issued patent, our well-established law places the burden of persuasion on the attacker to prove invalidity by clear and convincing evidence." Tech Licensing Corp., 545 F.3d at 1327. In this case NexMed has the ultimate burden of persuasion at trial to show that Mr. Heath and Beta infringed the '352 patent and Mr.

Heath and Beta have the burden of persuasion to prove the invalidity of the '352 patent.

ANALYSIS

Infringement

NexMed claims that Defendants infringed the '352 patent by selling the Beta Device to consumers, which induced those consumers to infringe the '352 patent. Defendants seek summary judgment on induced and direct infringement on the grounds that NexMed has not shown that Defendants knew or should have known that the '352 patent was valid and that consumers who purchased the Beta Device infringed the '352 patent. Defendants also argue that consumers cannot directly infringe the '352 patent by using the Beta Device because the Beta Device does not use constant direct current, a requirement of the '352 patent. Further, they argue that evidence that consumers purchased the Beta Device does not show infringement of the '352 patent because the Beta Device can be used in a noninfringing manner. NexMed counters that Defendants' knowledge of the outcome of the 0288 litigation demonstrates that the Defendants knew or should have known that they were inducing infringement of the '352 patent.

"Indirect infringement . . . can only arise in the presence of direct infringement." Dynacore Holdings Corp. v. U.S. Philips Corp., 363 F.3d 1263, 1272 (Fed. Cir. 2004). To show that Defendants induced others to infringe the method claims found in the '352 patent, NexMed "has the burden of showing that the [Defendants'] actions induced infringing acts and that [they] knew or should have known [their] actions would induce actual infringement." DSU Med. Corp. v. JMS Co., 471 F.3d 1293, 1304 (Fed. Cir. 2006) (en banc) quoting Manville Sales Corp. v. Paramount Sys. Inc., 917 F.2d 544, 554 (Fed. Cir. 1990). NexMed must also show that "each of the claimed steps of a patented process [are] performed in [the] infringing process." Canton Bio-Medical Inc. v. Integrated Liner Techs., 216 F.3d 1367, 1370 (Fed. Cir. 2000). When a patent

covers only method claims, "the sale of equipment to perform a process is not sale of the process . . . ." Ricoh Co. v. Quanta Computer Inc., 550 F.3d 1325, 1334 (Fed. Cir. 2008). If a device has "substantial noninfringing use, an evidentiary showing that the defendant intended that the [device] be used for direct infringement is required." Id. at 1341. Because each claim of the '352 patent "comprises" the elements that follow, "the listed elements (i.e., method steps) are essential but other elements may be added." Lucent Techs., Inc. v. Gateway, Inc., 525 F.3d 1200, 1214 (Fed. Cir. 2008); see also Conoco, Inc. v. Energy & Envtl. Int'l, L.C., 460 F.3d 1349, 1360 (Fed. Cir. 2006) (stating that "comprising" is a term of art in patent law).

Defendants argue that they had reason to believe the Beta Device was not capable of infringing the '352 patent because they believed the patent was invalid and they believed that the Beta Device was not capable of infringing. NexMed contends that Defendants' knowledge of the outcome of the 0288 litigation belies this argument. The court agrees with NexMed. A fact finder could reasonably infer that Defendants' knowledge of the 0288 litigation and its outcome shows that they knew or should have known that the '352 patent is valid and enforceable and that the Beta Device and accompanying instructions were similar enough to the infringing device in the 0288 litigation to be likely to infringe the '352 patent.

Defendants next claim that the Beta Device cannot be used to infringe the '352 patent because it employs variable, bidirectional direct current rather than constant, unidirectional direct current. As proof that the current in the Beta Device differs from that described in the '352 patent, Defendants point to the testimony of NexMed's expert, who stated that the current flowing from the Beta Device varies and that the current flows for 12.5 seconds in one direction before reversing and flowing for 12.5 seconds in the opposite direction. But these statements do not prevent the Beta Device from infringing the '352 patent. The prosecution history indicates

that the "constant" current requirement means that the current is not pulsed, not that the current travels at the same rate throughout its application. Further, the reversal of the current flow after 12.5 seconds of constant, unidirectional current does not prevent the Beta Device from infringing the '352 patent. The '352 patent specifies that the claims "comprise" the listed steps, meaning that so long as the elements stated in the claim are met, the process infringes the patent even if additional elements are added. Accordingly, a 12.5 second flow of unidirectional direct current can infringe the '352 patent if it is applied in accordance with the other steps.

Defendants also maintain that NexMed has failed to put forth evidence that consumers actually infringed the '352 patent. Defendants contend that NexMed did not put forth sufficient evidence of sales of the Beta Device within the United States. They also argue that the Beta Device can be used in a noninfringing manner. In contrast to the claims described in the '352 patent, Defendants argue that consumers can use the Beta Device for more than one minute at a time, at intervals greater than two hours, and after a herpes lesion has developed.

In response to Defendants' arguments, NexMed points to Chester Heath's October 16, 2007 deposition when Mr. Heath testified about sales of the Beta Device. NexMed also provided the court with supplemental materials, including Mr. Heath's booklet, "Learning to Smile Again," and the "Use/Apply" instruction sheet distributed with each sold Beta Device unit. The "Learning to Smile Again" booklet specifies that Beta Device users should place the probes around the affected area at least eight times a day. The "Use/Apply" sheet instructs users to reapply the electrical current "HOURLY if late and open sores, or Half Hourly if early and tingling." The '352 patent similarly directs that the electrical current should be applied to areas affected by the herpes virus "at hourly intervals for time durations of two to fifteen seconds for at least eight hours, after the onset of symptoms," and to areas with precursor symptoms "at regular

intervals of time of less than two hours over an extended period of time."

This evidence is sufficient to raise a question of fact about whether Defendants induced infringement of the '352 patent, and the court denies summary judgment for Defendants on direct and induced infringement.

Prosecution History Estoppel

Defendants argue that the prosecution history of the '352 patent invalidates the spacing requirements and limits the '352 patent to methods that use a constant direct current. "[P]rosecution history estoppel can occur during prosecution in one of two ways, either (1) when the applicant makes a narrowing amendment to the claim ('amendment-based estoppel') or (2) when the applicant surrenders claim scope through argument to the patent examiner ('argument-based estoppel')." Voda v. Cordis Corp., 536 F.3d 1311, 1325 (Fed. Cir. 2008) (internal quotations omitted). "To invoke argument-based estoppel . . . the [patent] prosecution must evince a clear and unmistakable surrender of subject matter." Conoco, Inc. v. Energy & Envtl. Int'l, L.C., 460 F.3d 1349, 1364 (Fed. Cir. 2006). Conversely, amendment-based estoppel places the burden on the patentee to show that the amendment was not added for a reason related to patentability. Id. at 1363. While it is unclear which type of prosecution history estoppel Defendants argue, it appears that their position is that NexMed surrenderred the spacing requirement and amended the current requirement.

The Defendants first contend that NexMed surrendered any claim that involved direct current that was not constant because the inventors responded to the patent examiner's objections by contrasting the constant DC method it proposed with prior art that used a pulsed DC. But the inventors' response means only that the patent does not cover pulsed current, not that the current needs to travel at a consistent speed between the probes. The Defendants' expert states that the

current in the Beta Device was not constant because it decreased during application, but he does not claim that the electrical current pulsed. The prosecution history does not demonstrate that a current that decreases during application falls outside the scope of the '352 patent.

Second, the Defendants argue that NexMed surrendered the spacing limitations during the patent examination when the inventors surrendered the device claims that contained spacing requirements. But Defendants cannot show that the patent prosecution shows a clear and unmistakable surrender of the subject matter when the spacing requirement remained in claim 7 of the original patent.

Defendants motion for summary judgment based on the prosecution history of the '352 patent is denied.

Ownership of Patent

Defendants contend that NexMed is not the valid owner of the '352 patent because two of the claimed transfers of ownership of the patent were invalid. The first invalid transfer, according to NexMed, took place in January 1993, when a partnership owned the patent. Dr. Lathrop and Mr. Johnston, members of the partnership, conveyed ownership to themselves as individuals excluding their third partner, Gloria Kent.

The next claimed invalid transfer occurred when Dr. Lathrop and Mr. Johnston assigned the patent to Target Capital, NexMed's predecessor, but no assignment was ever recorded with the USPTO. As a result of these allegedly invalid transfers, Defendants argue that NexMed does not have standing to bring an infringement suit. Moreover, according to Defendants, the '352 patent is invalid because NexMed concealed the ownership discrepancy during the first and second reexamination proceedings before the patent office.

"Generally, one seeking money damages for patent infringement must have held legal

title to the patent at the time of the infringement." Rite-Hite Corp. v. Kelley Co., 56 F.3d 1538, 1551 (Fed. Cir. 1995). Patents are "assignable in law by an instrument in writing." 35 U.S.C. § 261. An assignment need not be recorded with the patent office in order to be valid, but an unrecorded assignment is void against a subsequent purchaser. Id. An agreement to assign at some time in the future is not a sufficient writing to convey a patent. Gaia Techs. v. Reconversion Techs., 93 F.3d 774, 779 (Fed. Cir. 1996).

Defendants claim that the instrument that conveyed the patent from the partnership to Dr. Lathrop and Mr. Johnston was void because it was either "forged or fraudulent." But California Corporations Code section 15009 (repealed 1996) clearly allows every partner "the execution in the partnership name of any instrument . . . unless the partner so acting has in fact no authority to act for the partnership." Although it is possible that the patent was conveyed in violation of Ms. Kent's rights, Dr. Lathrop and Mr. Johnston had the right under California law to do business on behalf of the partnership. The excluded partner, Ms. Kent, may have had a cause of action against her partners for breach of fiduciary duty, but until she invalidated the conveyance through legal action, the conveyance was voidable, not void.

Defendants also maintain that Dr. Lathrop and Mr. Johnston never formally assigned the patent to Target Capital, although they agreed to do so in an Asset Purchase Agreement. The abstract of title for the '352 patent reflects a gap between the assignment from the partnership to Dr. Lathrop and Mr. Johnston as individuals and the assignment by NexMed, Inc., to NexMed Holdings. In response to the court's request for supplemental submissions, NexMed provided the document that assigned the rights under the patent from Dr. Lathrop and Mr. Johnston to Target Capital, the company that later became NexMed. Although the assignment was not recorded with the USPTO, it conveys a clear intent to transfer the patent to Target Capital and is

signed by both Dr. Lathrop and Mr. Johnston.

The court denies summary judgment for the Defendants on the ownership issue.

Public Use

The Defendants claim that the '352 patent is invalid for prior public use. Defendants point to two public uses. First, they claim that the clinical studies were prior public use because there were no secrecy agreements with users, no limits or instructions given to users, and no controlled study or records of the use. Second, they contend that Wendell Eves, former president of NexMed, received a device more than a year before the filing of the patent application that could be used to employ the method described in the '352 patent. NexMed argues that the clinical studies were not prior public use because they were experimental.

An invention cannot be patented if it has been in public use for more than one year before the initiation of a patent application unless the invention was not ready for patenting at the time it was available for public use. 35 U.S.C. 102(b); Pffaff v. Wells Elecs, Inc., 525 U.S. 55, 67 (1998). An invention is ready for patenting when it has been reduced to practice or when "the inventor ha[s] prepared drawings or other descriptions of the invention that [are] sufficiently specific to enable a person skilled in the art to practice the invention. Pfaff, 525 U.S. at 67-68. "Public use . . . includes any use of the claimed invention by a person other than the inventor who is under no limitation, restriction or obligation of secrecy to the inventor." Netscape Communs. Corp., 295 F.3d 1315, 1320 (Fed. Cir. 2002).

The existence of an invention in its final form does not establish that the invention was patentable if the inventor does not yet know whether the invention will work for its intended purpose. Astrazeneca v. Apotex Corp., 536 F.3d 1361, 1374 (Fed. Cir. 2008); see also New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co., 298 F.3d 1290, 1297 (Fed. Cir. 2002) ("What would

otherwise appear to be public use is negated if the inventor was testing claimed features of his invention."). "'The use of an invention by the inventor himself, or of any other person under his direction, by way of experiment, and in order to bring the invention to perfection, has never been regarded as [a public] use.'" Eli Lilly & Co. v. Zenith Goldline Pharms., Inc., 471 F.3d 1369, 1381 (Fed. Cir. 2006) quoting City of Elizabeth v. Am. Nicholson Pavement Co., 97 U.S. 126, 134 (1877). Experimental use does not necessarily require secrecy. Id. But "experimental use cannot negate a public use when it is shown that the invention was reduced to practice before the experimental use." Astrazeneca, 536 F.3d at 1372. "To demonstrate reduction to practice, a party must prove that the inventor (1) 'constructed an embodiment or performed a process that met all the limitations' and (2) 'determined that the invention would work for its intended purpose.'" Id. at 1374 (quoting z4 Techs., Inc. v. Microsoft Corp., 507 F.3d 1340, 1352 (Fed. Cir. 2007)); see also Juicy Whip, Inc. v. Orange Bang, Inc., 292 F.3d 728, 737 (Fed. Cir. 2002) ("When the asserted basis of invalidity is prior public use, the party with the burden of proof must show that 'the subject of the barring activity met each of the limitations of the claim and thus was an embodiment of the claimed invention.'") "On summary judgment, once [the moving party] presented facts sufficient to establish a prima facie case of public use, it [falls] to [the nonmoving party] to come forward with some evidence raising a genuine issue of material fact to the contrary." Netscape Communs. Corp., 295 F.3d at 1320-21; see also Hycor Corp. v. Schlueter Co., 740 F.2d 1529, 1535 (Fed. Cir. 1984) (stating that once the defendant has made a showing that public use occurred more than a year prior to the filing of the patent application, "the patent owner must come forward with clear and convincing evidence to counter that showing").

Defendants first argue that when Dr. Lathrop distributed devices described in the '352 patent to his patients that this was prior public use. Indeed, Mr. Johnston's declaration asserts

that several years before filing the patent application he provided devices to Dr. Lathrop to use with his patients to treat herpes sores and that these patients used the devices in the manner of use prescribed in the '352 patent, including the duration of application limitation, the frequency of use limitation, and the periodic use limitation. But he does not state that he knew at the time he provided the devices that the method worked to prevent or limit a herpes outbreak or that the use during these years was not experimental. For that reason, NexMed's argument that the use of the '352 method during this time was experimental is sufficient to create a genuine issue of material fact about whether the '352 patent was ready for patenting at the time Dr. Lathrop distributed it to his patients.

The second instance of prior public use, Mr. Eves's receipt and use of a device identical to the one described in the '352 patent, fails because Mr. Eves does not testify that he used the device in an infringing manner. The '352 patent is a method claim, so Mr. Eves's statement that he received a device capable of being used as described in the '352 patent more than a year before the filing of the patent application is not sufficient to show prior public use. Rather, his use of the device must be able to satisfy each limitation of the claim. His declaration does not demonstrate that his use satisfied this requirement. While he claims that the device met the spacing limitation, the duration of application limitation, and possibly the voltage limitation, he does not state that he applied the device at intervals described in the patent. (Dec. Wendell Eves, January 3, 2008.) As a result, the Defendants have failed to establish a prima facie case of prior use sufficient to shift the burden of production to NexMed.

The court denies Defendants' summary judgment motion on these grounds.

Usefulness

Both parties have raised the issue of usefulness in their summary judgment motions.

NexMed has asked the court to preclude the Defendants' second affirmative defense that the '352 patent is invalid because it is not useful. The Defendants have moved for summary judgment on their claim that patent '352 is invalid because it is not useful. Specifically, the Defendants argue that the '352 patent is not useful because it burns, injures, and causes welts, although they do not claim that the process does not treat cold sores. They also maintain that the failure to market a product that employs the method described in the '352 patent demonstrates its lack of usefulness.

To be patentable, a process must be "new and useful."[1] 35 U.S.C. § 101; see also, Brenner v. Manson, 383 U.S. 519, 528-29 (1966); In re Fisher, 421 F.3d 1365, 1371 (Fed. Cir. 2005) ("It thus is clear that an application must show that an invention is useful to the public as disclosed in its current form . . .[meaning] that the claimed invention has a significant and presently available benefit to the public."). "If the claimed subject matter is inoperable, the patent may . . . be invalid for failure to meet the utility requirement of § 101." Brooktree Corp. v. Advanced Micro Devices, Inc., 977 F.2d 1555, 1571 (Fed. Cir. 1992). "The threshold of utility is not high: An invention is 'useful' under [§] 101 if it is capable of providing some identifiable benefit." Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1366 (Fed. Cir. 1999). For the court to find that a patent has violated § 101 the patented claim "must be totally incapable of achieving a useful result." Brooktree Corp., 977 F.2d at 1571.

Defendants have submitted expert testimony that a device built as described in the '352

[1] NexMed argues that the '352 patent meets all requirements of 35 U.S.C. § 101 because it meets the machine-or-transformation test for patentable subject matter outlined in In re Bilski, 545 F.3d 943, 961 (Fed. Cir. 2008) (en banc). But the argument made by Defendants under § 101 is not that the subject matter of the '352 patent is not patentable. Rather, the Defendants argue that patent '352 is not useful, a separate requirement of § 101. See id. at 958 n.15.

patent burned those who used it.[2] Although the Defendants claim that the device was harmful and not useful, Defendants did not use the device on cold sores in the method described in the '352 patent. See, e.g., Pl.'s Br. Ex. 1 at 95:24. Their argument that the '352 patent causes harm does not show that the process is totally incapable of achieving a useful result. As NexMed argues, a harmful product may still be useful. For instance, radiation therapy can be harmful but still help to treat cancer.

Defendants' argument that the '352 patent must not be useful because it has not been marketed also fails to support their nonusefulness invalidity defense. The fact that NexMed never marketed a product that employed the patent '352 method does not, without more, demonstrate that the method is incapable of achieving a useful result.

The Defendants' summary judgment motion based on nonusefulness invalidity is denied. Because Defendants have only alleged that the '352 patent is harmful, not that it is incapable of curing herpes, the court grants summary judgment for NexMed on Defendants' Second Affirmative Defense.

Fraud on the United States Patent and Trademark Office

Defendants argue that NexMed made misrepresentations to the USPTO regarding a trademark they claim is associated with the '352 patent. As conceded by Defendants at oral argument on this motion, whether such misrepresentations were made is irrelevant to the validity of the patent. (Tr. Motion Hearing Jan. 22, 2010 at 68:21.) The court denies summary judgment on this issue.

Failure to Join Inventor

[2]Defendants have not produced the device they tested, and because the '352 patent contains only method claims, claims based on tests of the device Defendants created may not be relevant to the usefulness of the method described in the '352 patent.

Defendants argue that the '352 patent is invalid because the patent application incorrectly lists both Dr. Lathrop and Mr. Johnston as inventors. "[F]ederal law requires that the true inventorship entity be named in the patent application regardless of who owns the patent rights." Chisum § 22.02. Intentionally misrepresenting inventorship on a patent application invalidates the patent, but errors in listing inventors may be corrected. 35 U.S.C. § 256. "The inventors as named in an issued patent are presumed to be correct." Hess v. Advanced Cardiovascular Sys., 106 F.3d 976, 980 (Fed. Cir. 1997).

According to Defendants, the patent application listing both Mr. Johnston and Dr. Lathrop as inventors was in error. They point to Mr. Johnston's deposition testimony that the device described in the '352 patent was entirely his idea, not Dr. Lathrop's. But Mr. Johnston's testimony that the device that employed the patented method was entirely his idea cannot invalidate the patent under 35 U.S.C. § 256 because the '352 patent is not a device claim. Summary judgment for Defendants based on the misnaming of the inventor on the patent application is denied.

Inequitable Conduct (Fourteenth Affirmative Defense)

NexMed moves for summary judgment on Defendants' affirmative defense of inequitable conduct. If a patent applicant engages in inequitable conduct in obtaining a patent, meaning the applicant intentionally misrepresented facts, failed to disclose material information, or submitted false material information, the court should find the patent unenforceable. Baxter Int'l, Inc. v. McGaw, Inc., 149 F.3d 1321, 1327 (Fed. Cir. 1998). "Determination of inequitable conduct requires a two step analysis. First, the trial court must determine whether the withheld reference meets a threshold level of materiality. The trial court must then also determine whether the evidence shows a threshold level of intent to mislead the PTO." Id. "Intent to deceive cannot be

inferred from a high degree of materiality alone, but must be separately proved to establish unenforceability due to inequitable conduct." Astrazeneca Pharms. LP v. Teva Pharms. U.S., Inc., 583 F.3d 766, 773 (Fed. Cir. 2009). Information is material if "a reasonable examiner would have considered the information important in deciding whether to grant the patent." Id. The court considers the intent element of inequitable conduct separately from materiality. Id. at 776. "Evidence of mistake or negligence, even gross negligence, is not sufficient to support inequitable conduct in a patent prosecution." Id.

The Defendants put forth a number of alleged material nondisclosures omitted by NexMed in their patent application. They argue that NexMed failed to disclose that it did not own the '352 patent, that the '352 patent lacks utility, that there was an error in the listing of the inventor on the patent application, that the '352 patent had prior public use, that NexMed committed fraud on the USPTO with regards to a trademark attached to the '352 patent, and that NexMed concealed evidence of prosecution history estoppel. But they have put forth no evidence that NexMed intended to deceive the patent examiner.

The court grants summary judgment for NexMed on Defendants' Inequitable Conduct affirmative defense.

Patent Misuse (Fourteenth Affirmative Defense)

NexMed moves for summary judgment on Defendants' fourteenth affirmative defense, patent misuse. "Patent misuse is an affirmative defense to an accusation of patent infringement, the successful assertion of which requires that the alleged infringer show that the patentee has impermissibly broadened the physical or temporal scope of the patent grant with anticompetitive effect." Virginia Panel Corp. v. MAC Panel Co., 133 F.3d 860, 868 (Fed. Cir. 1997). "A patentee that has a good faith belief that its patents are being infringed violates no protected right

when it so notifies infringers." Id. at 869 (internal quotations omitted).

Defendants allege that NexMed engaged in patent misuse by sending a "cease and desist" letter to Beta's distributor, SkyMall, which caused SkyMall to remove Defendants' advertisement from its catalog. Defendants claim that this was patent misuse because NexMed did not hold a valid patent for a variety of reasons, and therefore informing SkyMall of its patent rights unlawfully expanded the scope of their patent from nothing. Regardless of whether the '352 patent is ultimately found to be valid, NexMed undoubtedly had a good faith belief based on the outcome of the 0288 litigation that its patent was being infringed. The letter did not expand the claims found in the '352 patent with anticompetitive effect and therefore did not amount to patent misuse. NexMed's motion for summary judgment on the Defendants' fourteenth affirmative defense is granted.

Unresolvable Ambiguity

Defendants argue that the patent is invalid because it is internally inconsistent and therefore violates 35 U.S.C. § 112(2)(4). Section 112 requires that a patent specification should distinctly claim the subject matter and states that dependant claims incorporate the limitations of the claim to which they refer. "A decision holding a patent invalid for indefiniteness presents a question of law." Exxon Research & Eng'g Co. v. United States, 265 F.3d 1371, 1376 (Fed. Cir. 2001).

The ambiguity at issue is the spacing of the electronic probes around the emerging herpes lesion. Claim 10 of the first reexamined patent specifies that the probes should be spaced between one-half inch to one-and-one-half inch apart, while claim 13, which is dependant on claim 10, specifies that the probes should be attached between three-quarters to one-and-one-half inches apart. This, according to the Defendants, leaves the public hopelessly confused about

whether they are violating NexMed's patent if they place probes between one-half and three-quarters inches apart. But claim 13 is "in accordance with claim 10" and considered dependant on that claim. For that reason, claim 13 incorporates the spacing limitation from claim 10, meaning that the '352 patent covers any spacing between one-half inch and one-and-one-half inch apart.

The Defendants' summary judgment motion based on patent '352's violation of 35 U.S.C. § 112 is denied.

Intervening Rights

Defendants insist that they had either absolute or equitable intervening rights to market the Beta Device because of the modifications to the original '352 patent made as a result of the first reexamination. "A reissued patent shall not abridge or affect the right of any person . . . who, prior to the grant of reissue," infringed a valid claim of the reissued patent which was not in the original patent. 35 U.S.C. § 252. Section 252 requires that the original patent claims and the reexamined patent claims be "identical" in order for the original patent to retain validity before the reexamination. "[I]dentical,' within the meaning of § 252 first paragraph, means 'without substantive change." Kaufman Co. v. Lantech, Inc., 807 F.2d 970, 977 (Fed. Cir. 1986) (finding that even though the patent examiner made clarifications in the reexamination that the substance of the claims was identical to the claims in the original patent). "If not 'identical,' the patentee has no right to recover infringement damages for periods prior to the date that the reexamination certificate issued." Tennant Co. v. Hako Minutemen, Inc., 878 F.2d 1413, 1417 (Fed. Cir. 1989) (finding that making a claim "more definite" was not a substantive change). Broadening of an original patent claim in a subsequent reexamination constitutes a substantive change to the claim. Seattle Box Co. v. Indus. Crating & Packing, Inc., 731 F.2d 818, 828 (Fed. Cir. 1984). At least

one federal court has found that narrowing of an original patent claim also constitutes a substantive change that would invalidate infringement claims that arose prior to the reexamination. In-Test Corp. v. Reid-Ashman Mfg., Inc., 66 F.Supp. 2d 575, 585 (D. Del. 1999).

The examiner in the first reexamination cancelled three of the original claims, amended six of the claims, and left four claims unchanged. The amended claims clarify the original patent by inserting limitations that were previously listed in the cancelled claims. For instance, the amendment of claim 5, an independent claim, inserts a spacing requirement that was previously listed as part of the cancelled dependent claim 6. Claim 7, which was previously dependant on claim 5, was converted to an independent claim and elements from claim 5 were added, including voltage, duration of treatment, and interval of treatment. Similar rearrangement took place within the other amended claims. Such amendments neither broadened nor narrowed the scope of the '352 patent. The claims covered by the '352 patent before the reexamination are identical to the claims in the reexamined '352 patent.

Accordingly, the court denies Defendants' Motion for Summary Judgment on Intervening Rights.

Willful Infringement

Defendants argue that they did not willfully infringe as a matter of law because they had reason to believe that the patent was invalid. "[T]o establish willful infringement, a patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent." In re Seagate Tech., LLC, 497 F.3d 1360, 1371 (Fed. Cir. 2007). The patentee must also show that the infringer knew or should have known of the high likelihood of infringement. Id. Whether an infringer acted

willfully is an issue of fact. Cohesive Techs., Inc. v. Waters Corp., 543 F.3d 1351, 1374 (Fed. Cir. 2008).

To demonstrate that in marketing the Beta Device Defendants reasonably believed that the Beta Device did not infringe on the '352 patent or that the '352 patent was invalid, Defendants list all of their defenses to the current infringement action. Defendants also argue that their awareness of the 0288 litigation indicates that they did not act willfully because they were not named in that case and could therefore assume that NexMed did not believe they were infringing the '352 patent. Plaintiffs counter that there is a triable issue of fact about whether the Defendants infringed willfully because their undisputed awareness of the '352 patent, the first and second patent reexaminations, and the 0288 litigation created an objectively high likelihood that their manufacture and sale of the Beta product infringed on the '352 patent. The court agrees that based on these facts a jury could find that Defendants willfully infringed the '352 patent. The court denies summary judgment for the Defendants on willful infringement.

Motions Regarding Damages Calculations and Equitable Relief

Defendants bring two motions relating to the calculation of damages and injunctive relief. They argue that the court should limit damages to a reasonable royalty rate and deny NexMed injunctive relief. They also seek to limit damages by asserting laches and equitable intervening rights. NexMed agrees that damages should be based on a reasonable royalty, but contests that injunctive relief is appropriate in this case and that the Defendants cannot assert equitable intervening rights or laches.

Defendants claim that the doctrine of laches bars NexMed from bringing suit against Beta and Mr. Heath because of the unreasonable delay between their discovery of infringement, as evidenced by the 0288 litigation, and filing suit. "Dismissal of a claim on the ground of laches

requires that there be (1) unreasonable and unexcused deelay in bringing the claim, and (2) material prejudice to the defendant as a result of the delay." Advanced Cardiovascular Sys. v. Sci Med Life Sys., 988 F.2d 1157, 1161 (Fed. Cir. 1993). A presumption of laches arises if there is six years or more of delay between the plaintiff's discovery of infringement and their filing of a lawsuit to enforce their patent rights. A.C. Aukerman Co. v. R.L. Chaides Constr. Co., 960 F.2d 1020, 1028 (Fed. Cir. 1992). A delay of less than six years may give rise to laches if the defendant is materially prejudiced by plaintiff's delay. Id. at 1033. The reason for the laches defense is to prevent patentees from "intentionally [lying] silently in wait watching damages escalate, particularly where an infringer, if he had notice, could have switched to a noninfringing product." Id. In this case there is no presumption of laches because there was at most four years of delay between the discovery of infringement and the initiation of the lawsuit.

Defendants have the burden to show that they have been materially prejudiced by the delay. They cannot make this showing because it is undisputed that they were aware of the '352 patent during the time prior to when NexMed filed suit. Defendants also have not shown that they are entitled to equitable intervening rights, as discussed above.

The court grants in part and denies in part the Defendants' Motion for Summary Judgment on Net Cash Flow Basis for Damages and their Motion for Partial Summary Judgment on Denial of Injunctive Relief and Limitations on Monetary Relief. Damages will be calculated based on a reasonable royalty rate, to be determined at trial. Summary judgment on Defendants' laches and equitable intervening rights arguments is denied. The court will decide whether an injunction is an appropriate remedy after the conclusion of a trial on the merits.

Motion to File Second Amended Answer

Defendants seek to file a second amended answer to assert an inequitable conduct defense

based on information not disclosed during the second patent reexamination. The court should grant leave to amend pleadings "when justice so requires." Fed. R. Civ. P. 5. "Refusing leave to amend is generally only justified upon a showing of undue delay, bad faith or dilatory motive, failure to cure deficiencies by amendments previously allowed, or undue prejudice to the opposing party, or futility of amendment . . ." Castleglen, Inc. v. Resolution Trust Corp., 984 F.2d 1571, 1585 (10th Cir. 1993).

A second amended answer by the defense made after the close of discovery and after all dispositive motions have been filed would create undue delay. In addition, because the affirmative defense that Defendants seek to add is substantially similar to its rejected eleventh and fourteenth affirmative defenses, such an amendment would likely be futile.

CONCLUSION

The court GRANTS Plaintiff's Motion for Summary Judgment Regarding Defendants' Eleventh and Fourteenth Affirmative Defenses (Dkt. No. 269) and Plaintiff's Motion for Summary Judgment Regarding Defendants' Second Affirmative Defense (Dkt. 271). The court DENIES Defendants' Motion for Summary Judgment on (1) Induced and Direct Infringement, (2) Prosecution History Estoppel, (3) Non-Ownership of Patent, (4) Public Use Invalidity, (5) Non-Usefulness Invalidity, (6) Fraud on the USPO, and (7) Failure to Join Inventor (Dkt. No. 280), Motion for Summary Judgment on Claim 13 Violates 35 U.S.C. § 112 (2)(4) (Dkt. No. 285), Motion for Summary Judgment on Intervening Rights (Dkt. No. 287), Motion for Summary Judgment on Willful Infringement (Dkt. No. 283). The court GRANTS in part and DENIES in part Defendants' Motion for Partial Summary Judgment on Denial of Injunctive Relief and Limitations on Monetary Relief (Dkt. No. 277) and Motion for Summary Judgment on Net Cash Flow Basis for Damages (Dkt. No. 292). The court DENIES Defendants' Motion to

File Second Amended Answer.

DATED this 17 day of March, 2010.

BY THE COURT:

Tena Campbell

TENA CAMPBELL
United States District Judge